

REMARKS

All the claims currently in this application have been made subject to a second restriction requirement. This second restriction requirement was necessitated by the amendment to the claims which prompted a reconsideration of the earlier imposed restriction requirement. As amended, the Official Action avers that there are two distinct and independent inventions embodied amongst the claims of the present application.

The first independent and distinct invention, as set forth in the outstanding Official Action, is denoted as Group I, encompassing Claims 1 to 10, 12 to 15, 28, 29, 31 to 39 and 44. These claims are alleged to be drawn to a method of preventing or treating stasis and pharmaceutical compositions, classified in Class 514, subclass 373.

The second distinct and independent invention alleged in the Official Action is directed to Claims 16 to 18, 20 to 27, 31 to 39, 42 and 44. These claims, expressed as the invention of Group II, are averred to be drawn to a method of treating or preventing gastrointestinal disorders and pharmaceutical compositions, classified in Class 514, subclass 373.

The Official Action argues that the inventions of Group I and II are distinct and independent insofar as the claims of Group I are directed to the treatment of patients suffering from hypomotility in the stomach whereas the invention of Group II requires a method of treating patients suffering from gastrointestinal disorders concomitant with other disorders unrelated to hypomotility. Thus, the Official Action avers that the methods of the claims of Groups I and II require treatment of patients suffering from different conditions, thereby requiring different treatment steps.

Applicants respectfully traverse this alleged distinction. Clearly, the background of the disclosure emphasizes that the conditions treated in accordance with the claims of Group II result from hypomotility in the stomach. The resolution of hypomotility in the stomach is emphasized as preventing or treating any of the gastrointestinal disorders recited in the claims of Group II. That is, the disorders treated by the compounds of the present application prevent or treat hypomotility in the stomach and any gastrointestinal disorders resulting therefrom. Thus, hypomotility and the resulting gastrointestinal disorders are cause and effect of the same physical condition. As such, applicants submit that all of the method claims currently in this application are directed to the same invention, in contradiction to the allegation made in the outstanding Official Action.

The above remarks emphasize the absence of distinctiveness between the claims of Groups I and II as defined in the outstanding Official Action. The absence of independence only further establishes the unitary nature of all the claims currently in this application.

That is, it is submitted that it is not possible for the issue of hypomotility in the stomach to be divorced from the gastrointestinal illnesses and conditions the prevention and treatment of which are the subject of the claims of the present application denoted as Group II. This is so insofar as it is hypomotility of the stomach that causes these illnesses and conditions.

That the two alleged distinct and independent inventions are classified in the same subclass further evidences applicants' allegation of the absence of independence and distinctiveness of the two sets of claims which are allegedly directed to distinct and independent inventions.

Attention is particularly directed to independent Claims 1 and 42 which are respectively directed to a method of treating or preventing stasis in all or any parts of the stomach and a method of treating or preventing gastric or gastrointestinal disorders. However, the characterizing portion of these claims are identical. It is thus not seen how treatment or prevention of stasis in the stomach, on the one hand, and treatment or prevention of a gastric or gastrointestinal disorder, on the other, which each employ the identical method, are independent and distinct of each other. In view of this fact applicants strongly urge that Claim 1, and the claims dependent therefrom, as well as Claims 42 and 43, and the claims dependent therefrom, are not distinct and independent. Reconsideration and removal of the restriction requirement of record is therefore respectfully solicited.

In addition to a restriction requirement, the outstanding Official Action requires an election of a species. Specifically, the Official Action states that the claims are directed to three patentably distinct species. Although the Official Action is silent as to what these three conditions are, it is presumed that these are the three conditions set forth in new Claim 43. Therein, a method of treating or preventing a gastric or gastrointestinal disorder in a mammalian patient is set forth. Applicants have elected, as the species to be prosecuted on the merits in this application in the event that a generic claim is not discovered encompassing all these conditions, condition (i) a sign or concomitant of diabetic neuropathy, anorexia nervosa, achlorhydria, gastrointestinal surgery, post-surgical recovery in the period of emergence from general anesthesia or the administration of morphine or morphine-like opioids. As required in a species election, applicants submit that Claims 1-10, 28, 29 and 44 read on this elected species.

Applicants traverse the imposition of the aforementioned species election. Applicants submit that the search required to identify prior art related to the three classes of conditions that are the subject of the present application does not involve an extended effort. This is so because all three conditions are predicated upon the same disease or condition. Indeed, condition (ii) is a secondary aspect of the primary disease or disorder which is the subject of the instant election. The third condition (iii) subject to the instant species election is an adverse side effect of a different therapeutic agent administered to the patient in the course of treating another unrelated disease or disorder. However, all three conditions result from hypomotility in the stomach. As such, they are not, in fact, different diseases but manifestations of the same basic disease. Reconsideration and removal of this species election is therefore deemed appropriate. Such action is respectfully urged.

The above remarks establish the inappropriateness of the imposition of a restriction requirement and a species election in the present application. Reconsideration and removal of these requirements, followed by examination on the merits and passage to issue of all the claims currently in this application, Claims 1-10, 12-18, 20-29, 31-39 and 42-44, is therefore respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Marvin Bressler", with a long horizontal flourish extending to the right.

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